

AA 9 [0018] Figures 5A and 5B together are an exemplary patient graph plotting pH levels over time, recorded by the embodiment shown in Figure 4, one sensor located proximally to the upper esophageal sphincter, and the other located distally to the UES, along with entered data marking episodes of heartburn, belching, and meals.

REMARKS

Statement Regarding Amendments and Embodiments of the Present Invention

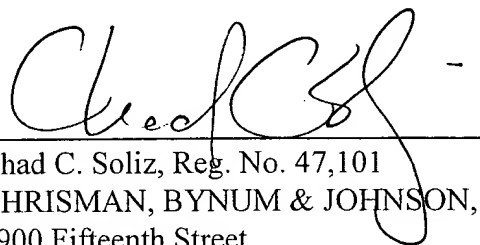
Amendments to the application have been made to address informalities, such as typographical and grammatical correction, in the written description and to bring the application into a formal status by providing an Abstract as indicated in the outstanding Notice to File Missing Parts. The present amendments are particularly presented to avoid, where applicable, prosecution history estoppel, or the like, and have been provided to specifically avoid the introduction of new matter to the application.

CONCLUSION

The written description has been preliminarily amended to address informalities, and an Abstract has been provided to bring the application into formal status per 37 C.F.R. § 1.72(b). Claims 1-74 remain in the application. The Applicant respectfully and earnestly requests early consideration of the present application.

Respectfully submitted,

Dated: _____



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the application:

An Abstract has been provided as follows:

ABSTRACT

Pharyngoesophageal monitoring systems are provided that monitor the environment of the pharynx and esophagus, and in some embodiments, detect and monitor refluxate, and may further record other physical episode data. The system may be provided, in some embodiments, as a bifurcated, adjustable, multiple internal reference probe, and methods thereof, to detect acid reflux and to monitor pH levels of acid reflux episodes simultaneously at multiple locations within the pharyngoesophageal passage. Some embodiments provide a recorder and one or a plurality of sensor arrangements, the recorder being responsive to the sensors and capable of correlation of signals generated by the sensor arrangements.

In the specification:

Paragraph 0002, on page 1, has been amended as follows:

[0002] The present invention relates generally to a probe for monitoring reflux of hydrochloric acid from the stomach into the esophagus, a condition known as gastroesophageal reflux disease[,] . [and more] More particularly, the present invention is directed to a bifurcated, adjustable, multiple, internal reference[,] probe for detecting [such] acid reflux and monitoring pH levels of acid reflux episodes simultaneously at multiple locations within the pharyngoesophageal passage.

Paragraph 0006, beginning on page 3, has been amended as follows:

[0006] However, for monitoring of gastroesophageal refluxate in patient-specific diagnostics of such otolaryngological symptoms and disorders as those described above, as well as in group

studies of gastroesophageal refluxate effects, it is often [desireable] desirable to have the antimony sensors positioned in specific locations in the pharynx (above the UES), proximal esophagus (below the UES), and distal esophagus (above the LES). For example, a physician might want a first antimony sensor positioned in the distal esophagus a specific distance, such as about 5 cm above the LES to detect and monitor when refluxate gets through the LES and into the distal esophagus, how acidic it is, and how long it remains in the distal esophagus before it clears. At the same time, the physician may want to also position a second antimony pH sensor a specific distance, such as about 3 cm, below the UES to detect and monitor when such refluxate gets all the way up to the proximal esophagus just under the UES, how acidic it is, and how long it remains in the proximal esophagus before it clears. It may be useful to also position even a third antimony pH sensor a specific distance, such as about 2 cm, above the UES to detect and monitor whether refluxate gets through the UES and into the pharynx, and, if so, how acidic it is, and how long it remains in the pharynx before it clears. However, the length of the esophagus, i.e., the distance between the LES and the UES, varies from person to person, so conventional probes or catheters with multiple pH sensors do not meet this requirement. Therefore, a need may have previously existed and may have been identified by those in the relevant fields as a deficiency in heretofore previous systems. A previous attempt described in the Shaker et al. article cited above may have addressed the issue by using two separate probes with two separate recorders simultaneously[---], a single-site pH probe and recorder made by Del Mar Avionics, Ervin, California, and a dual-site pH probe and recorder made by Synectics Medical, Inc., Irving, Texas, and then [correlated] correlating the data from both probes.

Paragraph 0008, on page 4, has been amended as follows:

[0008] Accordingly, it is an object of this invention to provide a system that adequately monitors the environment of the pharynx and esophagus, and in some embodiments, detects and monitors refluxate. A goal, therefore, is to provide an apparatus having one or multiple sensors, and in some embodiments pH sensors, and which is insertable into a person's pharynx and esophagus. [An object of the present invention is also to detect, monitor and record gastroesophageal refluxate at specific desired locations.]

Paragraph 0009, on page 4, has been amended as follows:

[0009] An object of the present invention is also to detect, monitor and record gastroesophageal refluxate at specific desired locations. A further goal is to detect, monitor and record [and] wherein distance between at least some of the pH sensors is adjustable, and in preferred embodiments, to accommodate positioning the pH sensors in different positions, respectively, and, in some embodiments, in relation to the person's LES, UES, and portions of the pharynx and esophagus, as well as to accommodate variations in distances between the LES's and UES's of different individuals. Another goal of this invention is also to provide an apparatus comprising a plurality of pH sensors that are adjustable in a catheter.

Paragraph 0010, on page 4, has been amended as follows:

[0010] Another object of the present invention is to simplify calibration and acquisition, recording and display of data regarding the pharynx and esophagus conditions and reflux data, such as pH, time, and external physical episode data, in a coherent manner.

Paragraph 0012, on page 5, has been amended as follows:

[0012] To achieve the foregoing and other objects and in accordance with the purposes of the present invention, as embodied and broadly described herein, the present invention may provide a system having a recorder, and in some embodiments, a recorder responsive to each of the pH probes. The present invention may, therefore, reduce instances of inaccurate readings, some inaccuracies occurring when a patient is required to manually track episodes of heartburn or pain, or events such as meals and recumbent periods, or when a monitoring system is used which [contain] contains segregated electrical circuits for tracking such information. In addition to the features briefly discussed in the foregoing summary, numerous features, along with their advantages, of the present invention will be apparent to those skilled in the art upon consideration of the following detailed description.

Paragraph 0013, on page 5, has been amended as follows:

[0013] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate preferred embodiments of the present invention, and, together with the descriptions, serve to explain principles of the invention.

Paragraph 0014, on page 5, has been amended as follows:

[0014] Figure 1 is a diagrammatic front elevation view of a monitoring system in accordance with one embodiment of the present invention shown positioned in a patient's pharynx and esophagus in a manner that represents its use during monitoring[;].

Paragraph 0018, beginning on page 5, has been amended as follows:

[0018] Figures 5A and 5B together are an exemplary patient graph plotting pH levels over time, [being] recorded by the embodiment shown in Figure 4, one sensor located proximally to the upper esophageal sphincter, and the other located distally to the UES, along with entered data marking episodes of heartburn, belching, and meals.